"An experienced surgeon knows when to cut or not to cut."

You are lucky. This morning I fought with a journalist from the Swedish Television.

She wanted an interview...

...about the allegations, and we decided to do it now instead.

This is Paolo Macchiarini, one of the world's best known surgeons-

-in one of his most difficult moments.

He had declined almost every interview, but he agreed to talk to me.

Perhaps he was hoping to get an fair chance-

-or that I at least would tell the story
with all its complexities.

He has gained attention around the world using artificial windpipes in his transplants.

Surgeons in Sweden have carried out the world's first transplant of a synthetic organ.

An 11-year-old boy has had pioneering treatment to rebuild his windpipe...

Macchiarini is trying come up with a solution to our lack of spare parts-

-when something breaks inside our bodies.

He has already tried to create the world's first windpipe out of plastic.

In what seems like the plot from a science fiction novel-

-researchers built a new windpipe...

Soon all the organs can be built in a lab.
So far 17 people around the world have received one of Macchiarini’s windpipes.

Soon you’ll be able to live a normal life again.

But many of them have died as a result.

-Is it one of the biggest medical scandals?
  -Yeah.

If you do experimental surgery on humans, and you know beforehand that it's a disaster...

He has been accused of falsifying results and of experimenting on humans.

Some of his operations are under police investigation-

-for causing bodily harm, and for manslaughter.

And yet he has got the support of the medical establishment.

Paolo Macchiarini is not guilty of misconduct in his research.
This means he is trusted by Karolinska institutet.

So who is Paolo Macchiarini? Is he a genius, or is he a fraud?

And how important is a human life at the cutting edge of medicine?

The road towards the answers proves harder than expected.

Can you switch off?

This is really important to me also.

Can you switch off this as well?

This is the last time.

-I didn't expect any of that from you. -But these questions must be asked.

-The way you do it is very harsh. -But it's the only way...
No, there are more gentle ways
to ask things.

-But you're not replying.
-I'm not? Good luck.

THE EXPERIMENTS

PART 1: THE STAR SURGEON

For me it all started at the end of 2014,
when Macchiarini was accused-

-of falsifying research results,
and of gross misconduct.

Could this really be true?
At Karolinska, the home of the Nobel Prize?

These were serious allegations.
What if it was true?

I decided to find out what had happened.

Soon I got to meet Paolo Macchiarini
at his lab in Karolinska institutet, KI.

So this...

The tissue renewal lab is 2525?
It doesn't work with my 2525.

I got my first surprise right away.

Macchiarini's base at KI seemed very small and modest.

Thank you.

But according to Macchiarini, big things were happening in this ordinary setting.

This is, I think, the most advanced lab that we do have here-

-in regenerative medicine, probably one of the most advanced in the world.

We have a series of devices and tools-

-to evaluate ex vivo, the organs,
whether biological or artificial.

Here we do everything from the brain to the heart, lungs, kidneys, intestine-
-to the urethra, and other... investigations.

Untold numbers of people die each year when their organs cease to work.

The lack of new organs is one of the biggest problems in the medical world.

It is this riddle that Macchiarini is trying to solve.

These containers hold organs from rats.

Hearts, kidneys, oesophagi, and tracheas.

Organs that will bathe in stem cells-
-and, perhaps one day in the future, become new artificial organs.

Macchiarini will revolutionise
the medical world if he succeeds.

The lab may be small, but it is still Macchiarini's main base in the world.

He travels constantly and collaborates with other scientists, especially in Russia.

The findings here you may apply perhaps in Russia?

The findings here will be available to everyone, because they will be published.

But by sharing the information we can move...

...at a higher speed and knowledge.

But the reason behind the current pressure is his work in Stockholm.

Attorney Chases Those Responsible for Deadly Windpipes

Leading Surgeon Is Accused of Misconduct
The Swedish Research Council
is stopping all payments to Macchiarini.

He is under investigation
for falsifying research results.

..illegal operations,
and may be charged with manslaughter.

Explain to me,
what is my interest in...

...doing illegal surgery or...

...fabricating or manipulating data.
    That would be foolish.

Being what the media calls me, a superstar,
    I am always Black Peter, the bad boy.

Being famous, you're very easy to attack...

...before even
    the final judgement has come.

I think it's quite unfair,
    and it has destroyed my reputation.
And my honourability.

And you know exactly that media don't come back-

-and they highlight the bad things, but not the good things.

Macchiarini was headhunted to Karolinska in 2010-

-to start up a centre for research and transplantation with new organs.

Please welcome Professor Macchiarini.

The world of academia competes over famous scientists like Macchiarini.

Through top scientists, a university can hope to get bigger discoveries and bigger grants.

The very best are recruited from all over the world.

The local time is 5:55 pm...
Russia has also invited Macchiarini.

I travelled with Paolo to Krasnodar, his second base.

It was the first of many journeys-

-as Macchiarini's story was bigger and stranger than I had expected.

-Hello!
  -Hello.

-How are you?
  -I'm fine.

-Like usually?
  -Like usually.

-What are you working on, Paolo?
  -I'm working for the university.

We are trying to create new organs.

Like Frankenstein.
It hit me how untouched Paolo seemed by the allegations.

It was as if it was just a minor glitch.

Macchiarini had his sights on something much bigger.

My dream would be, as I was saying... to avoid the surgery.

That's crazy, right, for a surgeon to be saying that, but...

...to, for instance, use the cells to restore the function of an organ, that would be perfect.

So cell therapy is, in my eyes, the future.

Paolo was hoping to change the very foundations of modern medical care.

-It's been a long fight for you to do this.
  -Oh yes.
Do you feel that you’re closer to succeeding now, than you’ve been before?

If I had more time to delegate to science without dealing with all these other issues-

-and complaints, and allegations, and attacks, and so forth, then yes.

So the allegations and the complaints, they hinder your work, they take up a lot of time?

Right now I’m doing almost only that-

-so clearly I cannot have a relaxed and creative mind... right now.

It’s been going on for six months.

Interesting. Something you can talk about?

No, because the deal was that we would not talk about this. Do you remember that?

Of course I remembered. Macchiarini let me into his world on one condition.
He wanted to wait before commenting on the allegations.

His Swedish employer, Karolinska institutet, was still investigating the case.

And we had to let the process run its course.

Perfect.

Later he would give me all the answers.

I like it. Changes...

-See you later, or tomorrow morning. 
  -Later or tomorrow morning at 6... 6:20.

See you. Cheers, Paolo, it was really nice.

Here in Southern Russia-

-Paolo is creating a centre for transplantation and research.
 Completely Russian and also world-leading.

The base of the project is Paolo's lab at the University of Krasnodar.

Hello, how are you? Wait! Elena... Oh, I'm sorry.

-We should come, because of...
-Now? OK, then you...

Elena Gubareva is the research director, and she has created an artificial diaphragm-

-which is one of the muscles we use when we breathe.

What she has done-

-is transplanting the entire diaphragm on the left side, which is... incredible.

Nobody has done that with that success rate.

But... nobody believes it.
Whether it is because it is coming from Russia-

-whether it is because I'm under investigation of these... allegations-

-whether it is because it's too incredible... So we're having problems publishing it.

But you will see how it works, and so forth, and so forth...

So that's...

...part of the challenge of this new field, this high technology-

-this new advanced field. Well, everything that's new scares us.

It's like Mahatma Gandhi.

First they don't believe you, then they criticise you, then they start to...

And when you die... "Oh, maybe he was right." Or she.
But I'm not Mahatma Gandhi.

OK, I think you should take your coat now.

Elena shows me the rest of the lab.

This is a controversial part of medical research, and few are allowed in.

OK, we should go to the animals.

These are cages for big animals, for pigs, which will come here in the future.

And these cages are for rabbits and rats. They live here.

This is for different types of investigations.

-Vasia. Are you ready?
-Just a minute.

OK. We will go to the surgical room to do all the steps of operation.
-Did you anesthetise them?  
  -Yes.

Are they asleep? They anesthetise rats. Now one of them is asleep.

You can see... Now we will bring it to the surgical room.

-Is it asleep? Will it work now? OK...  
  -Yes.

Experiments on cells alone are often not enough-

-to gain knowledge of whether a treatment method will work in the human body.

But if the experiments aren't performed on a person, you may need something else.

It might seem cruel, and at times it really is.

First you remove the diaphragm from the donor rat.
The muscle is then washed in strong chemicals until all the donor cells are gone.

You are then left with a dead scaffold of a diaphragm.

The scaffold is submerged in a solution of stem cells-

-from the rat that will receive the muscle.

The receiver rat is then opened up, and the old diaphragm is removed.

The new muscle scaffold is taken out of the bath and put into the receiver rat.

The idea is that the stem cells will trigger the body to create a new organ.

This is animals after treatment, and these two rats-

-are rats after orthotopical transplant of the diaphragm after six months.

They are absolutely healthy. They have no problem with their health.
-These two are basically world unique?
  -Yes.

-These two rats are supposedly the first animals to breathe with an artificial muscle.

A hundred years ago, everybody said that a heart transplant was impossible.

But now we can see that heart transplants...

...are not routine, but everybody knows that it's possible to do.

It's very important never to stop, but to try to do everything that you can.

-Bye.
  -Goodbye.

The more I saw, the harder it was not to be impressed.
What they tried to achieve was simply great.

To Gubareva and Macchiarini-

- it didn't seem to be a question of IF their new method would ever become reality-

- but rather of WHEN the breakthrough would come.

We started with the trachea, and now we are at the higher level of complexity-

- because the oesophagus needs to contract, the diaphragm needs to contract-

- so all these functional capacities need to be preserved.

We do hope that, possibly, in the middle of next year-

- we could think to, after having the Ethics Commission's clearance-

- to have the green light to do it on humans.

Paolo intends to go from rat to human
in just one year, which is very fast.

During this time he will also need to test his new artificial muscles on other animals.

In Sochi there is one of the world's largest facilities for experiments on monkeys.

Previously secret departments of the Soviet defence were located here.

Civilian scientists are now able to experiment on the thousands of monkeys that live here.

But the preparations for Paolo's work here in Sochi had been delayed.

Paolo seems stressed, and he urges them on.

-Hello, how are you?  
-Nice to meet you.

It's such a pleasure to meet you.

We are about four months...
We have a four months’ delay in the time schedule.

Because we haven’t done that much progress since we started.

And these research grants are so strict-

- that if we don’t provide results, we will not be able to continue.

- It’s probably...
  - It only lasts until the end of the year.

She wanted to know what time it concerns.

Yesterday.

My problem is that nothing happens, and I hate that.

It makes no sense, we talk and we talk, but nothing happens.

Last time we met in December. Now we are almost in April, and nothing has been done.
And clearly we cannot continue this way-

-because otherwise we need to take in the report of the project and say: "Njet."

"Njet" and "njet". Then it's very bad.

Unfortunately things need to be done.

Ladies!

Starting by doing tests in test tubes, followed by experiments on rats-

-moving on to bigger animals, and after that you start performing tests on humans-

-that's usually how medical science works, to avoid the risks getting out of hand.

If Paolo had always worked in this way, this film may never have happened.

But that's not the case.
A method similar to the one Paolo tests here, he has previously used on humans.

In 2008 he took that controversial step.

This is Claudia Castillo.

She sought Macchiarini’s help after one of her tracheas had closed up.

A defect which couldn't be corrected at this particular time.

We are simply removing the damaged windpipe-

-and substituting it for a donated windpipe without its own stem cells.

This was something completely new, tracheas and stem cells.

This is how it was explained to the world...

Paolo cut out a piece of the windpipe from a dead donor.
The piece was then washed clean from donor cells.

Then Claudia's cells were taken from her bone marrow.

The cleansed windpipe was submerged in Claudia's cell solution-

-and a piece of it was inserted into Claudia.

Because they are able to grow stem cells, she is first to receive a new trachea.

Claudia Castillo, aged 30 and a mother of two, has plenty to be happy about.

Even if Macchiarini had gambled heavily, it all seemed to have worked out.

The scientists believe that the technique can help up to 3000 more across Europe-

-and eventually tens of thousands more with diseases like cancer of the larynx.
Macchiarini's method became world news. The well-respected journal The Lancet-ranked his research study among that year's ten most important.

In this case it's not just a promise, we've achieved what we set out to do.

It's a major achievement in the history of medicine.

In a short space of time, Macchiarini goes on to transplant several tracheas.

In London he operates on a ten-year-old who was born with a trachea too small.

It saved his life and has been described as a kind of miracle.

And in Moscow, on a woman from Kazakhstan.

And in Florence, on a young British woman with cancer.
Macchiarini’s status as a star was now at its peak.

He was desirable prey for universities and hospitals around the globe.

In the end, he was hired in Russia and in Sweden.

Karolinska was overjoyed with him, and he was considered fantastic among surgeons.

Not only was he an extremely competent surgeon-

-he also seemed to be revolutionising the entire science.

I remember the first time I met him, in the beginning of 2011.

He was a very powerful and colourful person in many ways...

...and surrounded by a huge aura.

This is the future.
You were in awe of him, and you just absorbed it all.

"What an amazing person we have here!"

Karl-Henrik Grinnemo is a surgeon and researcher.

Together with Matthias Corbascio he was asked to help Macchiarini set it all up.

We helped him with the most basic of things-

- like establishing a facility, and showing him how to pay the bills...

We collaborated and applied for different grants together-

- like you normally do in a research environment.

Macchiarini was now commissioned to start up-

- an international centre for transplantation
and surgery at Karolinska.

He was meant to do research at the institute and also perform experimental surgery.

I saw great advantages with the entire concept.

I also felt that Paolo would get involved in a completely different context at Karolinska.

That we would finally be able to build a general thoracic surgical unit-

-with Macchiarini as its star.

Paolo had also been asked to do research on other vital organs.

I think you take for granted that things will just work.

I can't say I understood how it all worked-

-but I completely trusted that what they did was correct.
I thought it was incredibly exciting.

I was meant to focus on heart and lungs-

-while Paolo's team
would focus more on the airways.

They would create kidneys and oesophagi.

You would be part of a large team
creating new organs.

That was the feeling I got.

But the pressure was hard.

Paolo was expected to have started
ground-breaking operations within 3 months.

Months went by without Paolo
performing a single transplant.

And he was also facing other problems.

Paolo had carried out transplants
on nearly ten patients using his new method.

But several tracheas had started to collapse. How was this going to be solved?

Paolo had a new idea.

He would stop the transplants using donated windpipes-

-and instead manufacture artificial ones, out of plastic.

But who would be the experimental subject?

He came across a patient in Iceland:

An Eritrean guest student by the name of Andemariam Beyene.

Andemariam was studying geothermal energy.

He was finding it hard to breathe.

For a while he thought it was asthma,
but the drugs didn't help.

0312 00:32:02:16 00:32:05:18

It was then discovered that he had cancer of the trachea.

0313 00:32:06:12 00:32:09:22

In the beginning, he responded well to the treatment.

0314 00:32:10:01 00:32:16:03

The tumour receded. This type of cancer is fairly unusual in the trachea.

0315 00:32:16:07 00:32:21:11

The treatment seemed to work, but then the tumour began to grow again.

0316 00:32:21:21 00:32:26:00

In 2011, Andemariam's ability to breathe worsened.

0317 00:32:26:04 00:32:33:14

His doctor began to look abroad, and Karolinska suggested Macchiarini.

0318 00:32:34:10 00:32:37:11

A patient was referred from Iceland-

0319 00:32:37:15 00:32:43:10

-that was given, in Harvard, Boston, a life expectancy of six months-

0320 00:32:43:14 00:32:48:11

-because he had already been operated on. He had a shortness of breath.
The case was discussed here, multidisciplinary

-and we decided that there was a risk of suffocation.

We were in need of something now, and not tomorrow.

Paolo decided to try his new idea with plastic tracheas on Andemariam.

Compared to the old procedure, since 2008 we have a completely new approach-

-where we don’t use natural windpipes that are decellularised-

-but synthetic polymers to build a custom-made individual windpipe.

The operation was performed at Karolinska University Hospital in June 2011.

Grinnemo was one of several assisting surgeons during the surgery.
It was almost like being in a bubble while you were in there.

0331 00:33:59:21 00:34:05:11

You didn't really hear what people said, because you were so focused.

0332 00:34:05:15 00:34:10:15

Everybody involved was completely focused on a successful operation.

0333 00:34:12:13 00:34:15:08

Apply it to the surface here...

0334 00:34:15:21 00:34:19:03

I was convinced that it would work. Of course I was.

0335 00:34:19:07 00:34:24:17

It didn't even cross my mind that it might not work.

0336 00:34:34:20 00:34:40:22

The surgery was very difficult. We were three experienced surgeons at the operating table.

0337 00:34:41:01 00:34:44:10

It was one of the most difficult surgeries we did.

0338 00:34:44:14 00:34:49:05

And clearly, it was the first time that we used this material, which wasn't optimal-

0339 00:34:49:09 00:34:53:03

-because it was done in a hurry, and so forth.
You believed that the synthetic trachea would be populated with cells-

-and then grow to become a real windpipe?

Absolutely. I was convinced of it.

-Everybody in the room felt the same way?

-Yes, they did. And so...

The only thought we had was that it would be successful.

And when it was all over we were all on a high.

You were both tired and happy, and of course hungry.

I remember we all got into a car-

-and drove off to Max and bought hamburgers for everybody.

We stuffed our faces
and celebrated the successful surgery.

It was something of a "hallelujah moment". We felt that we had made history.

A ground-breaking surgery gave a man back his trachea and his life...

Just as they had hoped, Macchiarini and Karolinska got the world's attention.

It's his tissue and his cells, but they have differentiated from bone marrow cells-

-and become all the different cell types.

So it's a living, breathing organ at this point.

Over a month later, Beyene started breathing and is on the road to recovery.

He is soon to be discharged from the hospital and heading home to his family...

But things didn't look quite as good for Macchiarini’s patient Keziah Shorten-
-the young British woman who had received a donated trachea in Florence.

After some time, her doctors observed that the transplants had failed-

-and that her windpipe had loosened.

For a long time, her British doctors had been collaborating with Macchiarini.

But they were now handed a disastrous situation.

We were faced with a very difficult clinical problem here at UCL-

-of a girl aged 20 who had had a terrible carcinoma, cancer of the windpipe.

It had been operated on elsewhere.

She'd had the windpipe essentially removed, reconstructed in a different way,

-and that had all broken down.
However, having seen what had happened in Sweden, we felt this offered her some chance.

The plastic trachea Macchiarini had used on Andemariam-

-had been manufactured in London by one of Birchall's colleagues.

Birchall ordered one more, for Keziah.

We did put a synthetic... I was the one who stitched in the top end-

-and my colleague stitched in the bottom end of this synthetic implant.

You could tell it was too rigid, and you couldn't see any evidence of any cells.

Microscopically there may have been some cells. There was certainly no respiratory lining.

It was a bit of plastic, an expensive bit of plastic.
I couldn't see it working, 
and sure enough, it didn't work.

Keziah's trachea was made 
from the same plastic as Andemariam's.

It was a special plastic called POSS PCU.

The POSS PCU had not 
performed as well as we'd hoped-

-it hadn't integrated 
into its surroundings very well.

And it had become infected, principally 
with fungus, but also with some bacteria.

The two ends of the trachea were 
very loose, they had not integrated at all.

There were sutures holding it in place, 
but very loosely.

She remained on the intensive care unit 
at UCL for another six weeks-

-but then was able to be discharged back to 
Brighton to be with her family for a few months.
Keziah's condition worsened, and shortly afterwards she passed away.

-So the material doesn't really work?
   -In its present form...

...that particular material is not the solution to tracheal transplantation right now.

But the British surgeons weren't the only ones doubting Paolo's plastic tracheas.

A colleague of theirs, Pierre Delaere, was working in Belgium.

He was astounded to hear about Paolo's operation on Andemariam.

It's obvious that a synthetic trachea cannot transform into a living trachea-

-by applying bone marrow on it.

For me this was unbelievable.
No theoretical evidence, no experimental data...

...supporting the thesis of regeneration.

I knew beforehand that it would lead to a big disaster. You implant it in a patient-

-and you know that this patient will die.

This was so wrong. I wrote immediately a paper to the President of Karolinska-

-"Look what’s going on in your institution. It’s completely wrong."

Delaere warned the Vice-Chancellor at Karolinska, and claimed-

-that Macchiarini’s research studies were misleading, making people believe-

-that plastic tracheas worked, despite it being "physically impossible."

They made misuse of the hype around stem cells-
-to introduce
something completely impossible.

To keep it clear, if I had the choice between...

...a transplantation of a synthetic trachea
and the firing squad-

-I would certainly choose the last option-

-because this is the least painful
form of execution.

It can sound very cruel,
but that's the real situation.

KI ignored the warning, and the hospital
went ahead with the next operation-

-on an American suffering from cancer,
who had found Macchiarini on the Internet.

My name is Christopher Lyles,
I'm born and raised in Maryland.

Graduated from Morgan State University.
I have a four-year-old,
I want to see her grow.

I'm not going anywhere...

Lyles was operated on in November, 2011.
After barely four months he was dead.

Two out the world's three patients
with plastic tracheas were now dead.

But Delaere's warnings
never took hold in the media.

From the outside, it all looked good.

During the Spring of 2012, a German
TV crew began to follow Macchiarini.

The micro CT scan would be, eventually,
of some help as well.

Here are some shots
from the team's raw material.
It's feels like stepping into a time machine, as everything was caught on tape-

0427 00:43:23:00 00:43:27:22

-not least the difficulties surrounding Macchiarini's project.

0428 00:43:27:24 00:43:33:09

Please try and answer this question, because she is making me crazy, and I hate that.

0429 00:43:33:11 00:43:37:23

Through this material I made several serious discoveries.

0430 00:43:38:08 00:43:45:22


0431 00:43:51:02 00:43:54:12

Unfortunately, we've had a...

0432 00:43:54:16 00:44:00:19

The latest transplantation was unsuccessful, and the patient died.

0433 00:44:00:23 00:44:09:02

It helped us a great deal and gave us a lot of energy.

0434 00:44:09:06 00:44:15:22

Naturally, we've had to start over again-

0435 00:44:16:01 00:44:19:08

-to try to find out what went wrong.

0436 00:44:19:12 00:44:28:00
He didn't die as a result of the scaffold.

Paolo was well aware of the death, but it didn't seem to stop him.

Two patients will undergo transplantations in Russia, on July 19 and July 21.

It's a race against time. We have learned a lot.

A great deal.

If we gamma sterilise the scaffold, why should we treat it with ethanol?

Even though Paolo couldn't be sure why his patient had died-

-he still made plans for new operations.

In the US he collaborated with the biotechnical company Harvard Bioscience.

Here's how the President of the company presented the method...
Our bio reactor is about the size of a shoebox, and inside there is a rotating part...

Green manufacture the bioreactor where the tracheas bathe in stem cells.

Green described the method as magic, the plastic would come to life in no time.

-What is it made of?  
  -A plastic polymer material with pores.

The cells can settle into those pores and start to grow. It feels like home to them.

After a few days the patient's own blood vessels-

-grow into the scaffold and make it part of him.

-Are they actually growing and multiplying?  
  -That's exactly right.

But on the beach in 2012 the atmosphere was a little different.
Hi, David.

What I'm about to hear will come as a shock to me.

Listen. Basically what happens is that...

...the scaffolds dry out.

And this is the reason why, when I felt the scaffolds-

-they were completely welded wrong.

They were like the POSS PCU material that we implanted in Mr Beyene.

Paolo says there was something wrong with Andemariam's plastic trachea.

And not only with that one, but also with the new plastic tracheas.

Despite the problems being unsolved, he intended to go ahead with new operations.
I'm quite unhappy about this, because either we know exactly what's going on...

Seven people in my lab have worked 24 hours a day for the last three weeks-

-and then... this is shit now.

So I think we need to do everything again.

We've lost two weeks by doing this.

Macchiarini's team in Stockholm was desperately trying to solve the problems.

If you have a patient that dies because of a new technology, you always ask yourself...

"Did I do something wrong? Do I have the right to continue? Should I continue?"

"What should we do better?"

...so even with 25 these yellow things are appearing?
It's very draining.
It's not a pleasant sensation, at all.

Good. Thank you again
for your outstanding work.

But still you learn only by doing.

It's going to be quite difficult to distinguish
the two measurements that we get.

Difficult, but not impossible, right?

He should do it, he must do it.
There's no chances, or no choices.

I'm saying that we're still improving,
and we need to improve time over time.

And only by doing we improve.

All these studies are ongoing.
This could be the future. Thank you so much.

He is one of our leading scientists-
-and he's also a very capable surgeon.

This combination is quite rare. He's on a high international level.

It's the kind of surgeon I want on my team. As a patient I'd want Macchiarini to help me.

First and foremost, he is a very competent surgeon.

He is very experienced in transplantations, in tracheal surgery... in everything.

He is very much open to new ideas.

We need people like Paolo... to force the issue-

-to get the decision to say, let's just do this even though we don't have all the answers.

The idea of this tracheal transplantation is something magical.

He's the only one.
-But the results so far make you hopeful?
  -Oh yes, of course.

  Otherwise I would have already stopped.

  Paolo had the support of many, and you can view the setbacks in more than one way.

  Sure, two out of the three with plastic tracheas were dead.

  But you might also point out that one out of three was alive, making it a success.

  -So how do you feel physically?
    -I'm OK.

  We speak relatively...

  From time to time it was going to be positive, going OK.

  So... I'm very optimistic for the future.

  So how is this day for you, one year exactly after the operation on Andemariam?
I'm very pleased to see him doing so well.

And it's gratification for all the effort we have done in the past, and continue to do.

It is a major achievement for other patients that would need this type of transplantation.

What if the plastic method was fundamentally correct-

-but that the patients had been too ill?

On a benign disease you still need other tools, like stents or similar.

It impairs the quality of life, but does not put the patient's life at risk-

-as opposed to the malignant...

So far, Paolo had been allowed to use the plastic tracheas in order to save lives.

Now he wanted to test his method on healthier and stronger patients-
-who were not in any immediate danger of dying.

We have now clinical trial authorisation in Russia and another one in Italy.

In Italy it's for biological scaffolding, and in Russia it's for benign diseases.

Probably we'll get one in Sweden for malignant diseases...

Paolo had succeeded with something almost impossible.

After very few animal tests, he got the go-ahead for a study on humans.

He was to test the plastic tracheas in Russia-

-on otherwise healthy subjects who suffered from old injuries.

In choosing the right subjects, they looked closely at many candidates.
The winner got to record a video explaining why they should pick her.

Julia Tuulik won the chance to be the first experimental subject.

A teacher and former dancer from Saint Petersburg.

The German TV crew was also there. They would follow her operation.

My name is Julia Tuulik. In 2008, I was in a very serious road accident.

I had a tracheostomy inserted.

Now I have a tube that constantly grinds on me.

It hurts a lot when I speak, breathe, lie down, and sleep - always.

I have lost my health and my beauty.

My little boy is the only thing that
makes me happy. I’m so blessed to have him.

0534 00:54:28:20 00:54:34:05

But he has never heard his mother sing,
not even a lullaby.

0535 00:54:35:15 00:54:41:15

As you can see,
I’m a normal, nice young girl-

0536 00:54:41:19 00:54:46:06

-and I would like to live
like other normal people.

0537 00:54:46:10 00:54:52:20

I need the tracheal transplantation
developed by Professor Macchiarini.

0538 00:54:57:22 00:54:59:18

Well?

0539 00:54:59:22 00:55:05:21

Tell us about when you woke up this morning,
and about how you felt.

0540 00:55:06:00 00:55:08:13

I got myself ready.

0541 00:55:08:17 00:55:13:13

-Were you calm?
-Yes, shouldn’t I be?

0542 00:55:13:17 00:55:16:19

Aren’t you scared or worried?

0543 00:55:16:23 00:55:22:08
When you ask, I get the feeling that you're trying to get me worked up.

0544 00:55:22:12 00:55:29:01

No, for now I just take it one step at a time.

0545 00:55:40:06 00:55:46:08

Thank you for coming. This is the final brainstorming before the transplantation.

0546 00:55:46:12 00:55:49:15

As a matter of fact, the patient, Julia-

0547 00:55:49:19 00:55:53:24

-is the first patient entering a clinical trial.

0548 00:55:54:03 00:55:57:17

So tomorrow, we plan to do the first human, ever done-

0549 00:55:57:21 00:56:02:21

-laryngeal tracheal transplant, using bio artificial scaffolds.

0550 00:56:04:03 00:56:07:20

How are you feeling, waiting for your surgery?

0551 00:56:07:24 00:56:13:11

If you asked less I would be calm, but now I'm getting nervous.

0552 00:56:13:15 00:56:18:01

That was the penultimate question.
-It's as if it's all down to me.
  -That's right.

50% of the outcome
is dependant on your attitude.

Julia was about to receive
the world's fourth plastic trachea.

In Iceland was her only living predecessor,
Andemaria.

And at Karolinska in Stockholm
they awaited yet another patient.

Would the method prove genius-

-as Macchiarini was able to test it
  on subjects as healthy as Julia?

Would it be a success?

-Do you know the problem?
  -No, what is it?

One of the prostheses....
-They'd better not damage anything.
-Nothing will be damaged.

0564 00:57:30 00:57:35 00:57:35:14

Being at the cutting edge,
you are always wrong.

0565 00:57:36 00:57:41 00:57:41:15

Until sooner, more likely later,
you demonstrate the opposite.

0566 00:57:43 00:57:49 00:57:49:05

Why should I give up?
I'm not the type to give up.